



DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DoD-2023-HA-0020]

Proposed Collection; Comment Request

AGENCY: Defense Health Agency (DHA), Department of Defense (DoD).

ACTION: 60-day information collection notice.

SUMMARY: In compliance with the *Paperwork Reduction Act of 1995*, the DHA announces a proposed public information collection and seeks public comment on the provisions thereof.

Comments are invited on: whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; the accuracy of the agency's estimate of the burden of the proposed information collection; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

Mail: Department of Defense, Office of the Assistant to the Secretary of Defense for Privacy, Civil Liberties, and Transparency, 4800 Mark Center Drive, Mailbox #24, Suite 08D09, Alexandria, VA 22350-1700.

Instructions: All submissions received must include the agency name, docket number and title for this Federal Register document. The general policy for comments and other submissions

from members of the public is to make these submissions available for public viewing on the Internet at <http://www.regulations.gov> as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to Department of Defense, Washington Headquarters Services, ATTN: Executive Services Directorate, Directives Division, 4800 Mark Center Drive, Suite 03F09-09, Alexandria, VA 22350-3100, Angela Duncan, 571-372-7574.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Utilization of the Novel ECC Eagle External Condom Catheter System; OMB Control Number 0720-EECC.

Needs and Uses: There are numerous methods to manage urinary incontinence, from pads/diapers to condom catheters to invasive urethral foley catheters. Pads or diapers can lead to skin irritation due to their occlusive barriers which can leave skin moist and lead to breakdown. Current condom catheters can be difficult to size and cause skin breakdown and infections. They can also fall off in patients with a large suprapubic fat pad and a shorter penis. Foley catheters can be uncomfortable and can lead to urinary tract infections. Thus, there is a need for a better way to manage urinary incontinence in men. The ECC Eagle is a novel design for a condom catheter that is intended to be more comfortable and secure than current models. We need to ask patients questions on their experience with the ECC Eagle, the degree of urinary symptoms they experience and the impact this has on their lives. This information is vital to the development of this product.

Affected Public: Individuals and households.

ECC Eagle Patient Satisfaction Questionnaire

Annual Burden Hours: 0.8.

Number of Respondents: 10.

Responses per Respondent: 1.

Annual Responses: 10.

Average Burden per Response: 5 minutes.

Male Urinary Symptom Impact Questionnaire (MUSIQ)

Annual Burden Hours: 3.3.

Number of Respondents: 10.

Responses per Respondent: 2.

Annual Responses: 20.

Average Burden per Response: 10 minutes.

PROMIS General Life Satisfaction Questionnaire

Annual Burden Hours: 1.7.

Number of Respondents: 10.

Responses per Respondent: 2.

Annual Responses: 20.

Average Burden per Response: 5 minutes.

The respondents will be adult men with stress urinary incontinence. They will be responding to this information collection because this is required if they want to trial the novel ECC Eagle external condom catheter. Each collection instrument will be done electronically via Qualtrics, a secure web-based survey platform. Patients will access this via their smartphone. The results will automatically be received via Qualtrics when they submit the responses.

Participants in the ECC Eagle trial will get to keep the external condom catheter they used for the study. There is no other gift, payment, or incentive to participate.

Dated: March 15, 2023.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer,

Department of Defense.

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